either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

The cited references fail to teach every element of the claims. In regard to the method claims (claims 108-111, 116 and 117), EP '814 fails to disclose the diseases of claim 108. EP '814 describes the use of phospholipids as a tear substitute material. On page 3, fourth full paragraph, EP '814 states that "[i]t is believed that the film formed from the phospholipid acts as barrier, reducing evaporation of the aqueous layer, thereby preserving the tear film." Claim 108 relates to a totally different group of eye diseases that are not necessarily involved in the manifestation of dry eye, i.e. the disease may occur even under conditions where there is a natural process of lubrication of the eye. The present invention provides for a healing effect on corneal epithelial cells. The healing effect regenerates cells whenever the cells are lacking or damaged, not withstanding whether the natural lubrication process within the eye has been damage. There is no teaching in EP '814 that phospholipids or any other component of the present invention may be used for any other purpose other than the treatment of dry eye. Therefore, EP '814 cannot anticipate the method claims under 35 U.S.C. § 102(b).

In regard to the storage medium claims (claims 133, 137 and 138), EP '814 fails to teach a medium for the preservation of ***isolated*** cornea. EP '814 discloses the composition for the treatment of dry eye. The composition of EP '814 is to be applied to the eye as by topical

application to the ocular surface to form a barrier to reduce evaporation (see page 3, fourth full paragraph; and page 5, fourth full paragraph). This composition is to be applied to an intact, functioning eye. By contrast, the present invention is a medium for the preservation of ***isolated*** cornea. There is no teaching in EP '814 that phospholipids or any other component of the present invention may be used as a medium to preserve ***isolated*** cornea. Therefore, EP '814 cannot anticipate the storage medium claims under 35 U.S.C. § 102(b).

Likewise, Levine et al. fail to disclose a medium for the preservation of ***isolated*** cornea. Levine et al. describe the effect of raising plasma HDL concentration against LPS-induced endotoxic shock. According to Levine et al., reconstituted protein or peptide and expression of HU-A-I transgenes protect mice from a lethal dose of LPS while doubling the plasma HDL level resulted in a 3 to 4 fold increase in survival. Thus, it is suggested that HDL provides some protection against acute endotoxemia for individuals with high plasma HDL levels and that HDL or reconstituted HDL may be useful clinically in the prevention or treatment of septic shock. This reference does not disclose or suggest the preservation of ***isolated*** cornea by a medium containing HDL. The medium of the present invention is not a therapeutic agent *per se*. Therefore, Levine et al. cannot anticipate the claims under 35 U.S.C. § 102(b).

THE CLAIMS ARE NOT OBVIOUS

Claims 112-114, 129, 131, 132, 134 and 140 stand rejected under 35 U.S.C. § 103(a) as being obvious over EP '814 in view of Pflugfelder et al. (U.S. Patent No. 5,652,209) and Levin (U.S. Patent No. 5,023,090). Applicant respectfully traverses the rejection.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the

knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *See* MPEP 2143.

EP '814, Pflugfelder et al. and Levin, taken alone or in combination, do not teach or suggest all the claim limitations. The deficiencies of EP '814 are discussed above. The Examiner relies on Pflugfelder et al. to teach the use of growth factors, and on Levin to teach the use of fibronectin and laminin for the treatment of dry eye syndrome. However, because EP '814 is deficient is disclosing the combination of elements in independent claims 108 and 133, this deficiency is not satisfied by Pflugfelder et al. and Levin.

Furthermore, none of the claims 112-114, 129, 131, 132, 134 and 140 recites growth factors, fibronectin and/or laminin as alleged by the Examiner. Claims 112-113 require that "the disorders are manifested by a slow rate of regeneration of epithelial cells of the anterior segment of the eye." Claim 114 requires albumin. Claim 131 requires Lipofundin™. Claim 132 requires Intralipid™. Claim 134 requires Lipofundin™ or Intralipid™. Claim 140 requires Apolipoprotein A-I, Apolipoprotein A-IV, or a combination of both apolipoproteins. None of these limitations are taught by EP '814, Pflugfelder et al. and Levin, taken alone or in combination. Accordingly, EP '814 in view of Pflugfelder et al. and Levin do not render the claims obvious within the meaning of 35 U.S.C. § 103(a).

ALLOWABLE SUBJECT MATTER

Applicant gratefully acknowledges the Examiner's indication that claims 115, 118-128, 130 and 135 are free of the prior art and would be allowable if rewritten in independent form.

Applicant note, however, that claim 135 is also rejected under 35 U.S.C. § 102(b) as being anticipated by Levine et al. Examiner's clarification of this inconsistency is respectfully solicited.

CONCLUSION

Applicant has responded to the Office action mailed December 2, 2002. All of the claims are now believed to be allowable and favorable action is respectfully requested.

In the event that there are any questions relating to this Response or to the application in general, it would be appreciated if the examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Please charge any shortage or credit any overpayment of fees to BLANK ROME LLP, Deposit Account No. 23-2185 (000744-00077). In the event that a petition for an extension of time is required to be submitted herewith and in the event that a separate petition does not accompany this response, applicant hereby petitions under 37 C.F.R. 1.136(a) for an extension of time for as many months as are required to render this submission timely.

Any fees due are authorized above.

Respectfully submitted,

Date: February 28, 2003

By: _____
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